# GOOD SENSE OMEPRAZOLE- omeprazole tablet, delayed release L. Perrigo Company

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#### Perrigo Omeprazole Delayed Release Tablets 20 mg Drug Facts

#### **Active ingredient (in each tablet)**

Omeprazole 20 mg

#### **Purpose**

Acid reducer

#### Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

#### Warnings

**Allergy alert:** Do not use if you are allergic to omeprazole

#### Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**

These may be signs of a serious condition. See your doctor.

#### Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

#### Ask a doctor or pharmacist before use if you are

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

#### Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

#### **Directions**

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

#### 14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

#### Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

#### Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

#### **Inactive ingredients**

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

#### Questions or comments?

#### 1-800-719-9260

### Package/Label Principal Display Panel

See current Drug Facts

FDA APPROVED

Treats Frequent Heartburn!

24 HR

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

Wildberry Mint Coated Tablet

Compare to Prilosec OTC®

**Actual Size** 

SWALLOW – DO NOT CHEW

42 Tablets

Three 14-Day Courses of Treatment

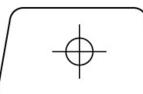
May Take 1 to 4 Days For Full Effect

3 Bottles Inside



SAFETY FEATURE - DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.





GOODSENSE.

NDC 0113-1723-03

See current Drug Facts FDA APPROVED

GOODSENSE.

Omeprazole



Treats Frequent Heartburn!

Delayed Release Tablets 20 mg Acid Reducer



Wildberry
Mint Coated Prilos ec OTC\*\* SWALLOW - DO NOT CHEW Treats Frequent Heartburn!

Delayed Release Tablets 20 mg

**Acid Reducer** 

Actual Size SWALLOW - DO NOT CHEW

Wildberry
Mint Coated PrilosecOTC\*\*



Treats Frequent Heartburn!

Delayed Release Tablets 20 mg Acid Reducer



Wildberry
Mint Coated
Tablet

Compare to
Prilosec OTC™

SWALLOW - DO NOT CHEW

Delayed Release Tablets 20 mg **Acid Reducer** Wildberry Mint Coated Tablet

MADE IN ISRAEL Distributed By Perrigo®

Allegan, MI 49010

**42** Tablets

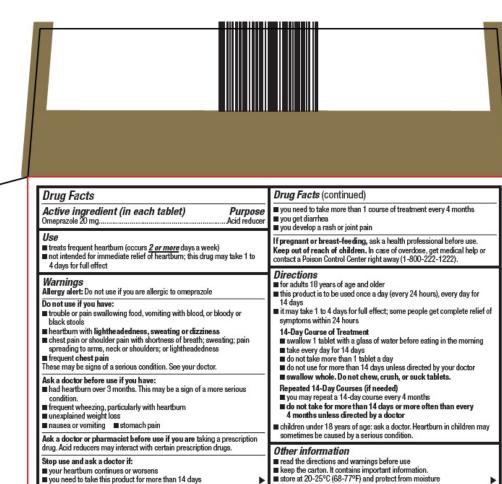
Three 14-Day Courses of Treatment May Take 1 to 4 Days For Full Effect

3 Bottles Inside



**CODE AREA** 

401D7 C2 C2



#### Drug Facts (continued)

#### Inactive ingredients

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolami polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

#### Questions or comments? 1-800-719-9260

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC\*.

3 Bottles inside

### Tips for Managing Heartburn ■ Do not lie flat or bend over after eating

- Do not wear tight-fitting clothing around
- the stomach
- Do not eat before bedtime ■ Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking





#### GOOD SENSE OMEPRAZOLE

omeprazole tablet, delayed release

<b>Product Information</b>	ct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-1723	
Route of Administration	ORAL			

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength OMEPRAZOLE OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9) 20 mg

### **Inactive Ingredients**

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MENTHOL (UNII: L7T10EIP3A)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics				
Color	PURPLE	Score	no score	
Shape	OVAL	Size	12mm	
Flavor	BERRY	Imprint Code	20	
Contains				

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:0113-1723-03	3 in 1 CARTON	05/22/2019		
1		14 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0113-1723-01	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2019		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA022032	05/22/2019		

## Labeler - L. Perrigo Company (006013346)

Revised: 6/2019 L. Perrigo Company